REMARKS/ARGUMENTS

ELECTION

The Examiner has repeated the assertion that the sequences of SEQ ID NO:4 and SEQ ID NO:6 represent different inventions. In particular, the Examiner states that the polypeptides do not share a common substantial structure or utility (March 19, 2008 Office Action, page 3).

Applicants timely traversed the restriction in the response submitted January 14, 2008, explaining that the two sequences represent variants of the same polypeptide. The "short form," *i.e.*, SEQ ID NO:6, is identical to SEQ ID NO:4 except for a deletion of 21 amino acids (positions 738-758 of SEQ ID NO:4). These polypeptides share the same essential structure, in that they share the functional actin-binding domain, and the unique C terminal domain found only in these prostate cancer-associated polypeptides (*see, e.g.*, paragraphs [0035] and [0040]of the specification, referring to the published application US20060160991). The unique C terminal domain of the polypeptides of both SEQ ID NO:4 and 6 and their unique, aberrant expression in prostate cancer make these polypeptides ideal diagnostic and therapeutic targets for prostate cancer.

However, in an effort to expedite prosecution, claim 1 is amended to exclude reference to SEQ ID NO:6, and claim 31 is canceled.

DECLARATION

The Examiner has objected to the original Declaration submitted November 28, 2005 for allegedly improper handwritten corrections in the document. Applicants made the corrections in the belief that they were in compliance with 37 CFR § 1.52(c). In an effort to expedite prosecution, however, Applicants submit herewith a new Combined Declaration and Power of Attorney.

PRIORITY

The Examiner has alleged that Applicants are not entitled to benefit from priority to U.S. Provisional Application 60/414,873, filed September 30, 2002, or the PCT Application PCT/JP03/12074, filed September 22, 2003. According to the Examiner, the provisional application does not include the polypeptide sequence of SEQ ID NO:4 or a nucleotide sequence that encodes the polypeptide. The Examiner concludes that Applicants are therefore entitled to the filing date of the present application, *i.e.*, November 23, 2005.

Applicants respectfully submit that the PCT application filed September 22, 2003 includes the sequence of SEQ ID NO:4. Applicants include **Exhibit A**, which includes the first page of WO04/031,231 and pages from the application showing SEQ ID NOs:3 and 4, *i.e.*, the nucleotide and polypeptide sequences of MICAL2-PV. Applicants therefore respectfully urge that the present claims are entitled to priority to the PCT application, filed September 22, 2003.

DRAWINGS

The Examiner has objected to the amino acid sequence depicted in Figure 1C without a sequence identifier. The Examiner requires Applicants to submit a corrected drawing sheet which includes the sequence identifier or, alternatively, to submit an amended description of the drawing, which includes the sequence identifier for the depicted sequence.

Applicants are selecting the option of submitting an amended description of the drawing, and therefore respectfully request withdrawal of the objection to Figure 1C.

SPECIFICATION

The Examiner has objected to the specification regarding: (1) reference to the amino acid sequence depicted in Figure 1C; (2) alleged improperly demarcated trademarks; and (3) allegedly improper embedded hyperlinks.

Applicants submit amended paragraphs to address each of these issues. As amended, paragraph [0034] (referring to the published application US 20060160991) explains that the sequence depicted in Figure 1C is SEQ ID NO:2. The remaining amended paragraphs

address the trademark and hyperlink issues, as well as minor typographical errors. Applicants therefore respectfully request withdrawal of the objections to the specification.

CLAIMS

Status of the claims

With entry of this amendment, claims 1 and 6 are pending. Claims 31 and 32 are canceled, and claim 1 is amended. Support for the amendments is found throughout the specification and drawings as originally filed, *e.g.*, in paragraphs [0040]- [0044] of the published application US 20060160991. Regarding the amino acid residues recited in amended claim 1, Applicants refer to **Exhibit B**, an alignment of the MICAL2-PV variants as described in the specification and sequence listing, which shows the recited amino acids from SEQ ID NO:4. No new matter is added.

Objection to the claims

The Examiner has objected to claims 1, 6, 31, and 32 as referring in the alternative to a non-elected invention. Solely in an effort to expedite prosecution, claim 1 is amended to remove reference to SEQ ID NO:6, and claims 31 and 32 are canceled. Accordingly, Applicants respectfully request withdrawal of the objection to the claims.

Rejection under 35 USC § 112, second paragraph

The Examiner has rejected claims 1, 6, 31, and 32 as allegedly indefinite for reciting the phrase "hybridizes under stringent conditions." The Examiner has also rejected claims 31 and 32 as allegedly indefinite for reciting the phrase "a pharmaceutically acceptable amount."

Solely in an effort to expedite prosecution, Applicants have removed the hybridization language from amended claim 1. Applicants have also canceled claims 31 and 32, rendering the second rejection moot. In so doing, Applicants make no admission as to the appropriateness of the rejection. In view of the amendments to the claims, Applicants respectfully request withdrawal of the rejection under the second paragraph of 35 USC § 112.

Rejections under 35 USC § 112, first paragraph - Written description

The Examiner has rejected claims 1, 6, 31, and 32 as allegedly failing to comply with the written description requirement. According to the Examiner, the specification only provides adequate description of the polypeptide of SEQ ID NO:4, because it allegedly fails to describe the structural and functional features of variants of SEQ ID NO:4 (*see* Office Action, page 12). To the extent to which the rejection applies to the amended claims, Applicants respectfully traverse.

Section 2163 of the MPEP sets forth the written description requirement as confirmed on multiple occasions by the Federal Circuit. The specification, drawings and claims as originally filed must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

The Revised Interim Written Description Guidelines, published March 25, 2008, provide examples of claims that comply with the written description requirement (*see* www.uspto.gov/web/menu/written.pdf). Example 10 analyzes a claim directed to variants of a protein that are at least 95% identical to a particular disclosed sequence and that have a particularly specified activity. The PTO concludes that "the genus of proteins that must be variants... does not have substantial variation since all the variants must possess the specific catalytic activity and must have at least 95% identity to the reference sequence." Thus, "the single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because the presence of an assay which applicant provides for identifying all of the at least 95% identical variants... which are capable of the specified catalytic activity." Accordingly, "one skilled in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus."

As amended, claim 1 part (b) is analogous to Example 10. Solely in an effort to expedite prosecution, claim 1 part (b) is amended to clarify both the structure and the function of the claimed polypeptides. In particular, the structure of variants of SEQ ID NO:4 includes

polypeptides with "ten or fewer amino acid substitutions, deletions, insertions, or additions." Functionally, the recited polypeptides bind actin and induce cell proliferation.

Amended part (b) is directed to an isolated nucleic acid having at least 98.9% identity to a reference sequence, namely, SEQ ID NO:4 (966/ 976 → 98.9%). Moreover, the function of actin binding and inducing cell proliferation is specified. Because the resulting species are defined in terms of both specific structure and function, the genus of polypeptides encompassed by the claim do not have substantial variation. Similar to Example 10, because the genus is not widely variable, the single species of SEQ ID NO:4 is sufficient to demonstrate possession.

Furthermore, as was the case in Example 10, the present specification sets forth assays for preparing an identifying such variants capable of actin binding and inducing cell proliferation. For example, paragraphs [0170]- [0181] describe detection of actin binding ability. Detection of cell proliferation can be detected by methods well known in the art, as described, for example, in paragraphs [0153]- [0160] and the Examples, paragraph [0260]. In addition, the specification provides methods of introducing mutations, *e.g.*, in paragraphs [0044]- [0052].

Regarding claim 1, part (c), Applicants submit that the recited polypeptide is described in the specification as filed. Paragraphs [0035], [0040], and [0258] and Figure 2 illustrate that the recited MICAL2-PV polypeptide variant has the same function as the polypeptide of SEQ ID NO:4. Applicants additionally provide **Ex. B**, which displays the amino acid residues of SEQ ID NO:4 included in the variant recited in part (c) of claim 1. Thus, the structure and function of the variant are specified sufficiently to meet the written description requirement.

In view of the foregoing remarks and amendments to the claims, Applicants respectfully request withdrawal of the rejection under the first paragraph of 35 USC § 112 for written description.

Rejection under 35 USC § 112, first paragraph - Enablement

The Examiner has rejected claims 1, 6, 31, and 32 as allegedly lacking enablement. According to the Examiner, the specification does enable making and using an

isolated polypeptide comprising the amino acid sequence of SEQ ID NO:4, an isolated nucleic acid molecule comprising a nucleotide sequence encoding said polypeptide, an isolated vector comprising said nucleotide sequence, and an isolated host cell comprising said vector. On page 17 of the Office Action, however, the Examiner alleges that the specification does not enable (1) the genus of polypeptides described in the claims or (2) use of the polypeptides to treat cancer (referring to claims 31 and 32). To the extent the rejection applies to the amended claims, Applicants respectfully traverse.

As explained in the MPEP at § 2164.01, the "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."

In an effort to expedite prosecution, claims 31 and 32 are canceled, and claim 1 is amended to clarify the genus of polypeptides included in claims 1 and 6. In so doing, Applicants make no admission regarding the appropriateness of the rejection.

Regarding the first aspect of the rejection, namely, that the specification does not provide guidance for the genus of polypeptides recited in the claims, Applicants submit that the claims as amended are enabled by the specification as filed. As explained above, amended claim 1 recites polypeptide variants of SEQ ID NO:4 with ten or fewer amino acid substitutions, deletions, insertions, or additions that bind actin and induce cell proliferation. Claim 1 also includes a variant of SEQ ID NO:4 comprising amino acids 1-737 and 759-976 of SEQ ID NO:4.

Given the present disclosure and knowledge in the art, one of skill could readily make and use the recited polypeptides. Methods of introducing sequence mutations are provided, *e.g.*, in paragraphs [0044]- [0052]. Methods of detecting the recited activities are provided, *e.g.*, in paragraphs [0153]- [0160] and the Examples (for inducing cell proliferation) and paragraphs [0170]- [0181] (for actin binding). Use of the claimed invention therefore would not constitute undue experimentation.

Regarding the second aspect of the rejection, Applicants submit that cancellation of claims 31 and 32 renders the issue moot. Accordingly, in view of the foregoing comments and claim amendments, Applicants respectfully request withdrawal of the rejection under the first paragraph of 35 USC § 112 for enablement.

Rejection under 35 USC § 102 - Ashida

The Examiner has rejected claims 1, 6, 31, and 32 as allegedly anticipated by Ashida, a UNIPROT sequence submitted February 15, 2005. The rejection is based on a priority date of November 28, 2005, asserted on page 5 of the Office Action.

As explained above under PRIORITY, Applicants submit that the present claims are entitled to a priority of the filing date of the PCT application, September 22, 2003. Accordingly, Ashida does not constitute prior art. Applicants therefore respectfully request withdrawal of the rejection under 35 USC § 102 based on Ashida.

Rejection under 35 USC § 102- Boehringer Mannheim Biochemicals catalog

The Examiner has rejected claims 31 and 32 as allegedly anticipated by the Boehringer Mannheim Biochemicals catalog from 1994, which discloses a kit with random primers. According to the Examiner, the random primer kit with all possible combinations of 6-nucleotide sequences anticipates a polynucleotide encoding a fragment of SEQ ID NO:4.

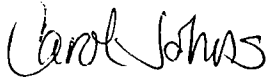
Solely in an effort to expedite prosecution, claims 31 and 32 are canceled. In so doing, Applicants make no admissions regarding the appropriateness of the rejection. In view of the cancellation of the rejected claims, Applicants respectfully request withdrawal of the rejection under 35 USC § 102.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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Attachments: Exhibits A and B
Declaration

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61379945 v1

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Declarations under Rule 4.17:

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: GENES AND POLYPEPTIDES RELATING TO PROSTATE CANCERS

(57) Abstract: The present application provides novel human gene MICAL2-PV whose expression is markedly elevated in prostate cancers. Furthermore, it provides polypeptides encoded by the gene as well as polypeptides encoded by PCOTH which expression was also discovered to be elevated in prostate cancers. The genes and polypeptides encoded by the genes can be used, for example, in the diagnosis of prostate cancers, as target molecules for developing drugs against the disease, and for attenuating cell growth of prostate cancer.

WO 2004/031231 A2

Exhibit A
10 Pages

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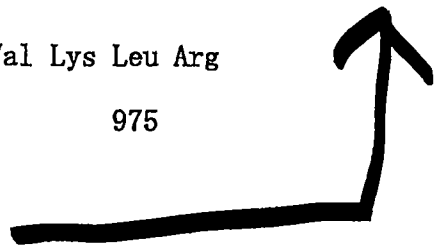

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Blast 2 Sequences results

NCBI | PubMed | Entrez | BLAST | OMIM | Taxonomy | Structure

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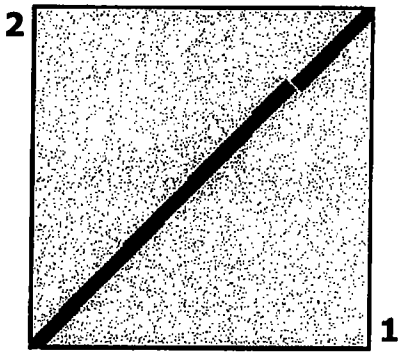

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            MGENEDEKQAQAGQVFENFVQASTCKGTLQAFNILTRHLDLDPLDHRNFYSKLKSKVTTW
Sbjct  1    MGENEDEKQAQAGQVFENFVQASTCKGTLQAFNILTRHLDLDPLDHRNFYSKLKSKVTTW  60

Query  61   KAKALWYKLDKRGSHKEYKRGKSCTNTKCLIVGGGPCGLRTAIELAYLGAKVVVVEKRDS  120
            KAKALWYKLDKRGSHKEYKRGKSCTNTKCLIVGGGPCGLRTAIELAYLGAKVVVVEKRDS
Sbjct  61   KAKALWYKLDKRGSHKEYKRGKSCTNTKCLIVGGGPCGLRTAIELAYLGAKVVVVEKRDS  120

Query  121  FSRNNVLHLWPFTIHDLRGLGAKKFYGKFCAGSIDHISIRQLQLILFKVALMLGVEIHVN  180
            FSRNNVLHLWPFTIHDLRGLGAKKFYGKFCAGSIDHISIRQLQLILFKVALMLGVEIHVN
Sbjct  121  FSRNNVLHLWPFTIHDLRGLGAKKFYGKFCAGSIDHISIRQLQLILFKVALMLGVEIHVN  180

Query  181  VEFVKVLEPPEDQENQKIGWRAEFLPTDHSLSEFEFDVIIGADGRRNTLEGFRRKEFRGK  240
```

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                VEFVKVLEPPEDQENQKIGWRAEFLPTDHSLSEFEFDVIIGADGRRNTLEGFRRKEFRGK
Sbjct  181    VEFVKVLEPPEDQENQKIGWRAEFLPTDHSLSEFEFDVIIGADGRRNTLEGFRRKEFRGK  240

Query  241    LAIAITANFINRNSTAEAKVEEISGVAFIFNQKFFQDLKEETGIDLENIVYYKDCTHYFV  300
               LAIAITANFINRNSTAEAKVEEISGVAFIFNQKFFQDLKEETGIDLENIVYYKDCTHYFV
Sbjct  241    LAIAITANFINRNSTAEAKVEEISGVAFIFNQKFFQDLKEETGIDLENIVYYKDCTHYFV  300

Query  301    MTAKKQSLLDKGVIINDYIDTEMLLCAENVNQDNLLSYAREAADFATNYQLPSLDFAMNH  360
               MTAKKQSLLDKGVIINDYIDTEMLLCAENVNQDNLLSYAREAADFATNYQLPSLDFAMNH
Sbjct  301    MTAKKQSLLDKGVIINDYIDTEMLLCAENVNQDNLLSYAREAADFATNYQLPSLDFAMNH  360

Query  361    YGQPDVAMFDFTCMYASENAALVRERQAHQLLVALVGDSLLEPFWPMGTGCARGFLAAFD  420
               YGQPDVAMFDFTCMYASENAALVRERQAHQLLVALVGDSLLEPFWPMGTGCARGFLAAFD
Sbjct  361    YGQPDVAMFDFTCMYASENAALVRERQAHQLLVALVGDSLLEPFWPMGTGCARGFLAAFD  420

Query  421    TAWMVKSWNQGTPPLELLAERESLYRLLPQTTPENINKNFEQYTLDPGTRYPNLNSHCVR  480
               TAWMVKSWNQGTPPLELLAERESLYRLLPQTTPENINKNFEQYTLDPGTRYPNLNSHCVR
Sbjct  421    TAWMVKSWNQGTPPLELLAERESLYRLLPQTTPENINKNFEQYTLDPGTRYPNLNSHCVR  480

Query  481    PHQVKHLYITKELEHYPLERLGSVRRSVNLSRKESDIRPSKLLTWCQQQTEGYQHVNVTD  540
               PHQVKHLYITKELEHYPLERLGSVRRSVNLSRKESDIRPSKLLTWCQQQTEGYQHVNVTD
Sbjct  481    PHQVKHLYITKELEHYPLERLGSVRRSVNLSRKESDIRPSKLLTWCQQQTEGYQHVNVTD  540

Query  541    LTTSWRSGLALCAIIHRFRPELINFDSLNEDDAVENNQLAFDVAEREFGIPPVTTGKEMA  600
               LTTSWRSGLALCAIIHRFRPELINFDSLNEDDAVENNQLAFDVAEREFGIPPVTTGKEMA
Sbjct  541    LTTSWRSGLALCAIIHRFRPELINFDSLNEDDAVENNQLAFDVAEREFGIPPVTTGKEMA  600

Query  601    SAQEPDKLSMVMYLSKFYELFRGTPLRPVDSWRKNYGENADLSLAKSSISNNYLNLTFPR  660
               SAQEPDKLSMVMYLSKFYELFRGTPLRPVDSWRKNYGENADLSLAKSSISNNYLNLTFPR
Sbjct  601    SAQEPDKLSMVMYLSKFYELFRGTPLRPVDSWRKNYGENADLSLAKSSISNNYLNLTFPR  660

Query  661    KRTPRVDGQTGENDMNKRRRKGFTNLDEPSNFSSRSLGSNQECGSSKEGGNQNKVKSMAN  720
               KRTPRVDGQTGENDMNKRRRKGFTNLDEPSNFSSRSLGSNQECGSSKEGGNQNKVKSMAN
Sbjct  661    KRTPRVDGQTGENDMNKRRRKGFTNLDEPSNFSSRSLGSNQECGSSKEGGNQNKVKSMAN  720

Query  721    QLLAKFEESTRNPSLMKQEKKSPSGFHFHPSHLRTVHPQESMRKSFPLNLGGSDTCYFCK  780
               QLLAKFEESTRNPSLMK                    QESMRKSFPLNLGGSDTCYFCK
Sbjct  721    QLLAKFEESTRNPSLMK--------------------QESMRKSFPLNLGGSDTCYFCK  759
                                737                 759
Query  781    KRVYVMERLSAEGHFFHRECFRCSICATTLRLAAYTFDCDEGKFYCKPHFIHCKTNSKQR  840
               KRVYVMERLSAEGHFFHRECFRCSICATTLRLAAYTFDCDEGKFYCKPHFIHCKTNSKQR
Sbjct  760    KRVYVMERLSAEGHFFHRECFRCSICATTLRLAAYTFDCDEGKFYCKPHFIHCKTNSKQR  819

Query  841    KRRAELKQQREEEATWQEQEAPRRDTPTESSCAVAAIGTLEGSPPGISTSFFRKVLGWPL  900
               KRRAELKQQREEEATWQEQEAPRRDTPTESSCAVAAIGTLEGSPPGISTSFFRKVLGWPL
Sbjct  820    KRRAELKQQREEEATWQEQEAPRRDTPTESSCAVAAIGTLEGSPPGISTSFFRKVLGWPL  879

Query  901    RLPRDLCNWMQGLLQAAGLHIRDNAYNYCYMYELLSLGLPLLWAFSEVLAAMYRESEGSL  960
               RLPRDLCNWMQGLLQAAGLHIRDNAYNYCYMYELLSLGLPLLWAFSEVLAAMYRESEGSL
Sbjct  880    RLPRDLCNWMQGLLQAAGLHIRDNAYNYCYMYELLSLGLPLLWAFSEVLAAMYRESEGSL  939

Query  961    ESICNWVLRCFPVKLR  976
```

```
            ESICNWVLRCFPVKLR
Sbjct  940  ESICNWVLRCFPVKLR  955


CPU time:      0.06 user secs.        0.04 sys. secs          0.10 total secs.
```